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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/009,317 | 05/15/2002 | Michael E. Selsted | P-UC 5042 | 6942 |
| 23601 | 7590 | 11/17/2004 | EXAMINER | |
| CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122 | | | DESAI, ANAND U | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/009,317 | SELSTED ET AL. |
| | Examiner | Art Unit |
| | Anand U Desai, Ph.D. | 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on September 7, 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 15-22,33-35,51-67 and 84-109 is/are pending in the application.
4a) Of the above claim(s) 55-67,91-105,107 and 108 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 15-22,33-35,51-54,84-90,106 and 109 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____ .

DETAILED ACTION

1. This office action is in response to Amendment filed on September 7, 2004. Claims 1-14, 23-32, 36-50, and 68-83 have been cancelled. New claims 84-109 have been added. Claims 15-22, 33-35, 51-54, 84-90, 106, and 109 are currently under examination.

Election/Restrictions

2. Applicant's election with traverse of Group I, pending claims 15-22, 33-35, and 51-54 in the reply filed on September 7, 2004 is acknowledged. The traversal is on the ground(s) that unity of invention does not apply for this national stage application, and that during the PCT stage no indication of a lack of unity requirement was presented. This is not found persuasive because under 35 U.S.C. 121 if two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. Further 35 U.S.C. 372 (a) states that all questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office. The inventions lack unity and are distinct as previously described in the requirement for restriction office action.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 55-67, 91-105, 107, and 108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 7, 2004. This application contains claims 55-67, 91-105, 107, and 108 drawn to an invention nonelected with traverse filed on September 7, 2004. A complete reply to the final

rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 120. The priority date is May 10, 1999.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on July 12, 2002 is being considered by the examiner.

Specification

6. The disclosure is objected to because of the following informalities:
7. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should

follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Suggest, "This application is a national stage of PCT/US00/12842 filed May 10, 2000, which is a continuation-in-part of U.S. Application Ser. Num. 09/309,487, filed May 10, 1999, now U.S. Pat. No. 6,335,318."

Appropriate correction is required.

Claim Objections

8. Claims 106, and 109 are objected to because of the following informalities:
9. Claims 106, and 109 depend from withdrawn claims 105, and 108.

Appropriate correction is required.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 15-22, 33-35, 51-54, 84-90, 106, and 109 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 23-25, 41-44, and 68 of copending Application No. 10/313,994 (US 2003/0162718 A1). Although the conflicting claims are not identical, they are not patentably distinct from each

other because the claims of the instant application are drawn to theta defensin polypeptides, pharmaceutical compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin, and a method of expressing a theta defensin polypeptide, and the claims to the copending application are drawn to theta defensin polypeptides, pharmaceutical compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin, and a method of expressing a theta defensin polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 15-22, 33-35, 51-54, and 84-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16, and 17 of copending Application No. 10/427,715 (US 2004/0014669 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to theta defensin polypeptides, pharmaceutical compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin, and the claims to the copending application are drawn to theta defensin polypeptides, pharmaceutical compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 15-22, 33-35, and 84-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 23-25 of U.S. Patent No. 6,335,318 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a theta defensin polypeptide, and a pharmaceutical composition comprising a theta defensin polypeptide, and the claims of U.S. Patent 6,335,318 B1 are drawn to an isolated theta defensin polypeptide, and pharmaceutical composition comprising theta defensin polypeptide.

14. Claims 106, and 109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,514,727 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a method of expressing theta defensin polypeptide, and the claims of U.S. Patent 6,514,727 B1 are drawn to a method of expressing theta defensin polypeptide.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 15-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The composition is directed to a product of nature absent the word, "isolated" or "purified" prior to theta defensin.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 15-22, 33-35, 51-54, 84-90, 106, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. In claims 15, and 19, the SEQ ID NO: 30 and 31 are not the same as the computer readable form (CRF) of the sequence listing? The CRF discloses nucleic acid sequence for SEQ ID NO: 30 and 31, while claims 15 and 19 are claiming amino acid sequences.

Art of Record

Tang et al. (Science Vol. 286, pp. 498-502 (October 15, 1999)) disclose a cyclic antimicrobial θ -defensin polypeptide. The posttranslational processing of two truncated α -defensin polypeptides produced the cyclic polypeptide. The disclosed cyclic polypeptide differs from the currently

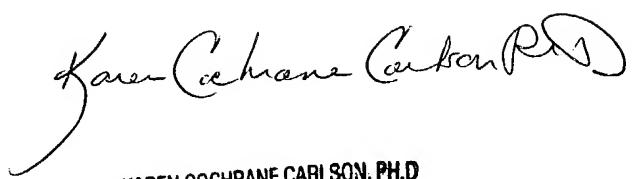
claimed polypeptide of claim 15 in amino acid positions 6 (Leu instead of Ile), 8 (Arg instead of Thr), and 11 (Val instead of Phe), and the claimed polypeptide of claim 19 in amino acid positions 2 (Val instead of Phe), 15 (Leu instead of Ile), and 17 (Thr instead of Arg).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 15, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER